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Implants of Gore-Tex

Comparisons With Teflon-coated Polytetrafluoroethylene Carbon and Porous Polyethylene Implants

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• **Pieces of an expanded, fibrillated, polytetrafluoroethylene material (Gore-Tex), were evaluated as implants for application in facial plastic augmentation and reconstructive surgery. The Gore-Tex cylinder material, which has an average internodal spacing of 30 μm, became permeated with viable connective tissue. Few histiocytes and giant cells accumulated at the implant site, a sign that little chronic inflammation and foreign-body reaction were present. Mature connective tissue around the implant appeared to form a strong supporting envelope for the material, yet the implant could be easily dissected from the subcutaneous tissue and could be removed en bloc without difficulty. Gore-Tex is a versatile material that seems to have a favorable future in facial plastic and reconstructive surgery. Clinical studies will define that potential more clearly.**

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Knowledge requisite to the practice of medicine rests upon... studies of living men in health and disease; studies of dead men, and correlated studies upon the lower animals.... Clinical science has the long-established right to wander unimpeded into any branch of medical science in search of information directly relevant to the problems of human disease.

SIR THOMAS LEWIS[1]

Most facial plastic and reconstructive surgeons, confronted by numerous challenges in cosmetic and functional reconstruction, prefer to use autogenous bone and cartilage because they are biocompatible. However, preserved allogeneic cartilage or bone (homografts) or synthetic materials must be used in reconstructive operations when autogenous tissue is unavailable. A variety of synthetic materials is readily available for soft-tissue augmentation.[2] The use of synthetics can allay some of the problems associated with obtaining autografts and preserving allografts. Unfortunately, the incidence of infection, rejection, and other associated problems may be unacceptable, particularly in nasal reconstructive surgery, where the thin covering of skin and frequency of trauma tend to potentiate these problems.

Autogenous bone, cartilage, and other connective tissues are certainly biocompatible; however, the degree of absorption is somewhat unpredictable, the grafts may warp and become distorted, and harvesting usually requires an operation at another site, which sometimes prolongs the operation time, increases the incidence of postoperative morbidity, and creates a cosmetic deformity at another site.[3,4] Allogeneic bone and cartilage (homografts) can be harvested from cadavers, subjected to radiation or freezing, and stored for long periods.[5] But again, the degree of absorption is somewhat unpredictable. For these reasons, great demand exists for an "ideal" synthetic material for nasal-facial augmentation and reconstructive procedures.

Because reports in the literature of the outcome of various implants are conflicting and often anecdotal, this study was designed to systematically investigate and objectively evaluate several forms of a relatively new material, polytetrafluoroethylene (Gore-Tex), and to compare it with

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two other materials, Teflon-coated polytetrafluoroethylene carbon (Proplast) and porous polyethylene (Plasti-Pore), which are well known.

REVIEW OF THE LITERATURE

In detailed overviews of the literature on various implant materials,[2,6] one finds that many inorganic materials, eg, gold, silver, aluminum, marble, cork, vitallium, tantalum, and ivory, have been used. Augmentation by injection of petrolatum, paraffin, and celluloid has been attempted. In the 1940s, plastic materials became widely used. Initial enthusiasm involved three classes of plastics—the methyl methacrylates (ie, Plexiglas, Paladon, Piacryl, and Palavil), the polyamides (ie, Perlon, nylon, and Supramid), and polyethylene. During the 1960s, there was a great deal of interest in silicone rubber. Enthusiasm for most of these, except polyamide mesh (Supramid) and polyester fiber suture (Mersilene[7-9]), has waned. Migration from the site of implantation, infection, and extrusion were common, presumably because the materials were not incorporated into the tissues. There is some concern about experimental induction of sarcomas by plastic materials.

The need for safe and compatible synthetic materials and for new developments in manufacturing are well known. Recently, detailed studies of polyamide mesh polytetrafluoroethylene carbon, porous polyethylene, and Silastic were done in rabbits to compare their biocompatibilities.[10] Silastic was not securely incorporated in the recipient site and was easily displaced, a well-known clinical observation. Polyamide mesh contains black pigment, but the pigment was not grossly apparent and the material became securely incorporated. It seems to be satisfactory in clinical practice, and the incidence of long-term complications appears to be low.[7,8,11]

Another synthetic material, polytetrafluoroethylene carbon, was studied in experimental sinus cavity obliteration, in soft-tissue implantation, and in middle ear surgery.[12-14] It is manufactured from two polymer families—polytetrafluoroethylene (Teflon) and pyrolytic graphite (carbon). The bulk chemistry, surface area and geometry, dynamic mechanical characteristics, and surface chemistry of the material have all been reported as favorable; however, it is black, it tends to shrink and pucker the overlying skin, and it induces a chronic inflammatory reaction.[10,12-13]

Porous polyethylene is one of the most recently described synthetic materials. It is a porous substance composed of high-density polyethylene and is classified as a springy polyprophylene. Bone permeates the material when the pore size is approximately 100 to 135 μm.[10,15] It has been used in middle ear surgery.

The occurrence of infection is always of concern in any grafting procedure, particularly when synthetic materials are used. Little has been done to study the interactions between bacteria and various synthetic materials, with the exception of the work by Kiechel et al,[16] Merritt et al,[17] and Karlan et al.[18] A higher incidence of infection is associated with silicones than with fluorocarbon and bioglass implants. It could only be concluded that there were important differences in the incidence of infection with similar implant surface structures.[18] The data relating the rate of infection and implant porosity are conflicting. In short-term animal models, the infection rate with porous materials was greater; in the long-term model, the infection rate was greater with dense materials after tissue invasion.[17] One would expect that materials with pores that exclude WBCs but not bacteria would be subject to a higher incidence of infection. That subject and the mechanisms of bonding of cells to implant materials are poorly understood.

In studies of various implant materials, it is important to know about their chemical and physical properties, eg, surface properties, heat resistance, surface area, geometry of the surface (porosity and spaces), dynamic mechanical characteristics (consistency, fatigability, long-term structural integrity, hardness, and elasticity), and the potential to induce malignant change. In a more practical sense, surgeons are most concerned about compatibility. The major considerations are migration-dislocation, discoloration, incidence of infection, ease of removal, ability to carve and shape, autoclaving requirements, and cost. Compatibility is best assessed in vivo, first in animals and then in clinical trials. Observations in animals should be made on a long-term basis, preferably for one year.

MATERIALS AND METHODS

Animals

Twenty-nine postpubescent New Zealand white rabbits, 6 to 10 months old and weighing 3 to 5 kg, were used in the experiments. Recipient sites for the various implant materials were the perichondrial space of the pinna and the subcutaneous tissues of the face and paraspinal region.

Implants

Three types of synthetic implant materials were evaluated—Gore-Tex, Teflon-laminated polytetrafluoroethylene carbon, and porous polyethylene.

Gore-Tex is expanded, fibrillated polytetrafluoroethylene. The unique structure is composed of nodules of solid polytetrafluoroethylene interconnected by thin, flexible fibrils of polytetrafluoroethylene. The material is manufactured in various fibril lengths, and the length of the fibrils determines the accessibility of the open spaces to infiltration by connective tissue. The major medical application of this material is in vessel replacement.[19] The material is produced from pure polytetrafluoroethylene in a process developed by W. L. Gore & Associates during the late 1960s. Animal studies began in 1970, and the first human vessel replacement procedures began in late 1971. The vascular grafts have a high bursting strength, high suture-holding capacity that resists pull-out, excellent handling characteristics, and good biocompatibility. On the basis of the experimental studies and the human work with the vascular grafts, the material seemed to be desirable for facial plastic reconstructive surgery.

Accordingly, three types of Gore-Tex materials were implanted in rabbits: (1) industrial membrane, 0.25-mm thick with an internodal spacing of 10 μm (Fig 1, top); (2) patch material, 1.1- or 1.7-mm thick with an internodal spacing of 10 μm (Fig 1, center); and (3) cylinder material, with an internodal spacing of 30 μm, cut to various thicknesses (Fig 1, bottom).

In previous experiments, Brown et al[10] evaluated polytetrafluoroethylene carbon

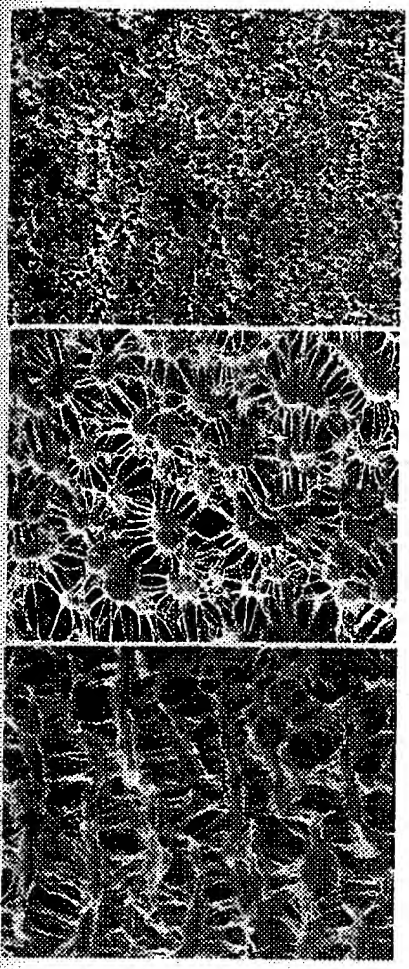
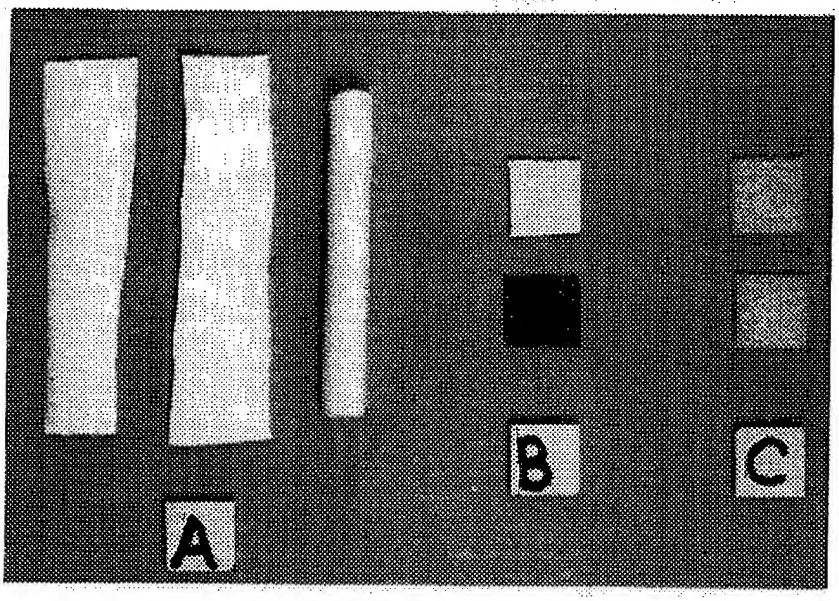


Fig 1.—Scanning electron micrograph of polytetrafluoroethylene nodes interconnected by thin fibrils—Gore-Tex. Top, Industrial membrane (sheeting), in which average internodal space is 10 μm (×2,000). Center, Patch material, in which average internodal space is 10 μm (×2,000). Bottom, Cylinder (rod) material, in which average internodal space is 30 μm (×1,000).

Fig 2.—Implant materials. A, Gore-Tex industrial membrane (at left), patch (at center), and cylinder (at right). B, Squares of Teflon-coated polytetrafluoroethylene carbon material (Proplast) 10 × 10 mm. C, Squares of porous polyethylene (Plasti-Pore), 10 × 10 mm.



in detail. Because the black material could be seen through thin skin and because the material is widely used elsewhere and is potentially of use in cosmetic surgery, Teflon-laminated sheets, 0.7-mm thick (0.3 mm of polytetrafluoroethylene carbon and 0.4 mm of Teflon on one surface) were evaluated in this study. Polytetrafluoroethylene carbon is 70% to 90% porous and has a mean pore size of 200 to 500 μm. It is prepared from Teflon fluorocarbon polymer and carbon fibers. The carbon adds strength and renders polytetrafluoroethylene carbon wettable to body fluids. This property, it is suggested, permits precipitation of proteins in a denatured form to reduce the rejection process. The Teflon lamination imparts a white appearance to one side (Fig 2). Polytetrafluoroethylene carbon is offered as the preferred implant for total ossicular replacement prosthesis, facial contour deficiencies, clinical augmentation, and alveolar ridge augmentation.

In another study, porous polyethylene at pore sizes of 20 to 30 μm was evaluated.[10] The material is rather rigid and not infiltrated at all with connective tissue; therefore, in this study, pieces of porous polyethylene 0.4-mm thick with a pore diameter of 175 μm were evaluated (Fig 2) to determine if this material in a more porous form would be more firmly incorporated into the recipient site and not subject to displacement by trauma.

Experimental Groups

The 29 rabbits were divided into groups to compare the various materials at the three recipient sites. Gore-Tex patch material was implanted in six rabbits, membrane material in six rabbits, and rod material in five rabbits. Porous polyethylene and polytetrafluoroethylene carbon with Teflon each were implanted in six animals.

Assessment of Recipient Sites

During the postoperative period, the recipient sites were examined every one to three days for signs of seromas, flap (skin) necrosis, infection, rejection-extrusion, scar formation, warping, and distortion. Flap necrosis, if any, was recorded as a percentage of flap necrosis, and the degree of implant extrusion was reported as either partial or total. Seroma formation was recorded. A scale of 0 to +3 was used, in which 0 meant none was present, +1 was minimal or few, +2 was moderate, and +3 was large, extensive, or many. Each observation was scored, and the mean score was recorded.

The animals were killed by administering a lethal dose of pentobarbital sodium six weeks, six months, or 12 months after surgery. The ears were shaved on both surfaces, and the recipient sites in the pinnae, face, and back were excised widely and fixed in 10% buffered formaldehyde solution for at least one week. With a rotary microtome, step sections were taken at approximately 3-mm intervals through the implant and surrounding tissues. Each specimen was stained with hematoxylin-eosin and evaluated microscopically by three observers.

The cellular responses associated with the implants were studied at ×44, and the number of histiocytes, giant cells, lympho-

Table 1.—Seroma Formation Around Pinna Implants

Implant	No. of Ears	Grading*			
		0	1	2	3
Gore-Tex					
Patch	12	5	7	0	0
Membrane	12	6	6	0	0
Cylinder	10	5	5	0	0
Porous polyethylene (Plasti-Pore)	12	6	5	1	0
Polytetrafluoroethylene carbon (Proplast)	12	1	4	4	3

* 1 indicates small; 2, moderate; and 3, large.

Table 2.—Skin Flap Necrosis Over Pinna Implants

Implant	No. of Ears	Degree (%) of Necrosis				
		0	25	50	75	100
Gore-Tex						
Patch	12	10	2	0	0	0
Membrane	12	7	3	2	0	0
Cylinder	10	10	0	0	0	0
Porous polyethylene (Plasti-Pore)	12	1	4	1	4	2
Polytetrafluoroethylene carbon (Proplast)	12	5	2	3	1	1

Table 3.—Extrusion of Pinna Implants

Implant	No. of Ears	Implant Extrusion	
		Partial	Total
Gore-Tex			
Patch	12	0	0
Membrane	12	0	0
Cylinder	10	0	0
Porous polyethylene (Plasti-Pore)	12	4	3
Polytetrafluoroethylene carbon (Proplast)	12	1	2

Table 4.—Relative Numbers of Histiocytes (Macrophages) and Giant Cells at Implantation Sites

Implant	Duration*		
	6 wk	6 mo	1 yr
Gore-Tex	+2	+1	+1
Porous polyethylene (Plasti-Pore)	+1	+1	+1
Polytetrafluoroethylene carbon (Proplast)	+3	+3	+2

* +1 indicates few; +2, moderate number; and +3, many.

cytes, polymorphonuclear leukocytes, and plasma cells were graded at ×10, with the same grading system, to report the findings.

Operative Technique

Anesthesia was induced with pentobarbital, 30 to 35 milligram per kilogram of body weight, which was injected into the saphenous vein of either hind leg. The technique of implantation in the ear has been described previously.[3,10] A broadly based flap of skin and perichondrium based anteriorly was elevated from the cartilage on the ventral (concave) surface of each ear; an operating microscope was used for magnification (×6). A 10 × 10-mm template was used to demarcate the piece of cartilage to be removed. The scored 10-mm-square piece of cartilage was removed, and the perichondrium beneath the cartilage was preserved. A 10 × 10-mm piece of test substance was then sutured into the defect with two 4-0 plain catgut sutures at opposite corners. The flap was replaced, and the skin edges were approximated with a continuous 4-0 plain catgut suture.

The facial implant sites were shaved and washed with alcohol and thimerosal. Two parallel incisions were made down to the periosteum in the skin of the forehead between the eyes. Subcutaneous pockets were fashioned, one inferiorly from the lower incision and another superiorly from the upper incision. A band of tissue approximately 1 cm wide between the incisions was not disturbed. A piece of test material was then placed in each pocket, well away from the line of incision. The wounds were closed with interrupted 4-0 plain catgut sutures.

The recipient sites along the dorsal paraspinal region were prepared. A transverse incision was made on each side of the spine, and small subcutaneous pockets were developed on the paraspinal muscles. The test material was tucked into the pockets, and the incisions were closed with 4-0 interrupted chromic catgut sutures. Each rabbit was given 600,000 units of penicillin G benzathine intramuscularly in the hind leg.

RESULTS

Gross Examination

In the recipient sites in the face and back, the incisions healed promptly, and there was no evidence of seromas, hematomas, flap necrosis, infection, warping, or extrusion of any of the implants.

The pinna of the ear, however, again proved to be an excellent site to assess biocompatibility in terms of seroma formation, flap necrosis, and implant extrusion. The pinna is subjected to frequent movements, and the skin of the pinna and that overlying the implants is thin. Small seromas appeared at the Gore-Tex recipient sites in about half of the ears; no moderate or large seromas were observed with this material. However, seromas developed in most of the porous polyethylene and polytetrafluoroethylene carbon recipient sites in the ear, and they were of moderate to large size in eight (33%) of the 24 ears (Table 1). The incidence of grade 2 and 3 seromas was significantly less in the Gore-Tex group by χ^2 analysis ($P < .001$). The seromas persisted for a longer period in the polytetrafluoroethylene carbon group.

A striking difference was also seen in the incidence of flap necrosis at the ear implantation sites. Again, the Gore-Tex materials were most biocompatible by this criterion. In only two of the 34 implantation sites did

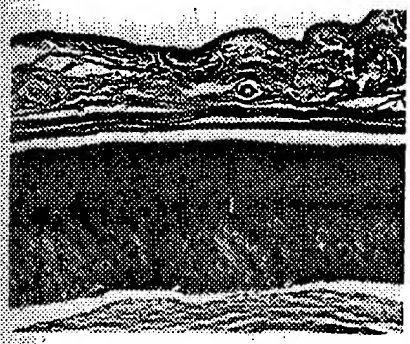


Fig 3.—Gore-Tex patch material implant (I) in pinna does not appear securely embedded in tissue (hematoxylin-eosin, ×64).

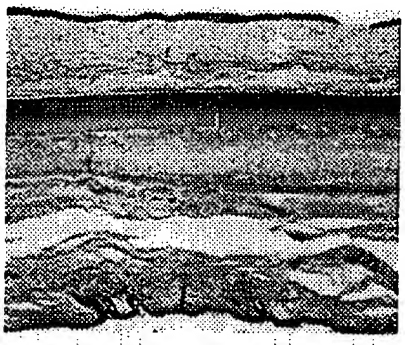


Fig 4.—Gore-Tex industrial membrane material in pinna. New cartilage can be seen in perichondrium, which was preserved when piece of cartilage was removed and implant was inserted. Implant (I) does not appear to be anchored firmly, although some tissue is attached to surface of specimen (hematoxylin-eosin, ×64).

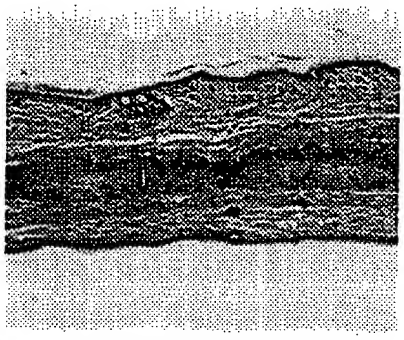


Fig 5.—Gore-Tex cylinder (rod) material in pinna. Implant (I) is firmly anchored, and interstices of cylinder material are partially filled with thin collagenous matrix, fibroblasts, and functional capillaries. There is good surface attachment (hematoxylin-eosin, ×64).

Fig 6.—Teflon-coated polytetrafluoroethylene carbon (Proplast) implanted subcutaneously in face. Thin connective-tissue layer beneath implant (I) is adjacent to periosteum of frontal bone. Higher-power views show moderate to large number of histiocytes and foreign body giant cells around and within implant (hematoxylin-eosin, ×64).

Fig 7.—Polytetrafluoroethylene carbon (Proplast) implant in pinna. New cartilage formation is apparent, but polytetrafluoroethylene carbon has virtually disintegrated, and there are large numbers of histiocytes and foreign-body giant cells. Although chronic inflammatory reaction persists at one year, implant (I) appears stabilized in connective tissue (hematoxylin-eosin, ×64).

the degree of flap necrosis approach 50%; in both instances, the material was the thin-membrane type, which has small internodal spaces. In contrast, the degree of flap necrosis exceeded 50% in six of the 12 ears with porous polyethylene implants and in two of the 12 ears with polytetrafluoroethylene carbon implants. Seven of the 12 ears with porous polyethylene implants had 50% or greater flap necrosis, and five of the ears with polytetrafluoroethylene carbon implants had 50% or greater flap necrosis (Table 2). The occurrence of necrosis was significantly less in the Gore-Tex implant group than in the polytetrafluoroethylene carbon implant or porous polyethylene implant group ($P < .001$).

There were no instances of either partial exposure or total implant extrusion with the Gore-Tex materials (Table 3). Portions of the porous polyethylene implants in the ear became exposed in four ears, and there was total extrusion of the porous polyethylene implants in three others. Therefore, there was partial or total extrusion of seven (58%) of the 12 porous polyethylene implants. A portion of one of the polytetrafluoroethylene carbon implants became exposed, and two others were extruded. Therefore, three (25%) of the 12 polytetrafluoroethylene carbon implants were either partially or totally extruded. The incidence of extrusion when Gore-Tex was compared with porous polyethylene and polytetrafluoroethylene carbon was significantly less ($P < .001$).

A particularly important observation was that, despite the Teflon layer of the black polytetrafluoroethylene carbon implants, gray discoloration was clearly visible beneath the skin. This was observed throughout the course of study and when the animals were killed at six weeks, six months, and 12 months. No discoloration could be seen beneath the thin ear skin over the Gore-Tex and porous polyethylene materials.

Microscopic Findings

The relative numbers of histiocytes and giant cells at the various implantation sites—in the ears and subcutaneously in the face and back—are given in Table 4. The cellular reaction in the vicinity of the Gore-Tex and porous polyethylene implants was minimal in the specimens six months and 12 months after implantation. In and around the polytetrafluoroethylene carbon implants, however, there was a profusion (+3) of these cell types, and this was noted at six weeks and six months postoperatively. The reaction diminished to moderate (+2) at one year.

The three types of Gore-Tex material were analyzed separately. The microscopic evaluation of the patch material disclosed slight tissue attachment to the surface of the material, but there was no evidence of cellular or tissue penetration into the material. There were a few scattered histiocytes and giant cells along por-

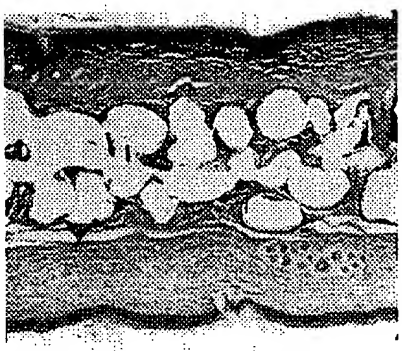


Fig 8.—Porous polyethylene (Plasti-Pore) implant in pinna is thoroughly infiltrated with connective tissue containing capillaries. Few histiocytes and giant cells are seen. Material (I) appears securely anchored in implantation site (hematoxylin-eosin, ×64).

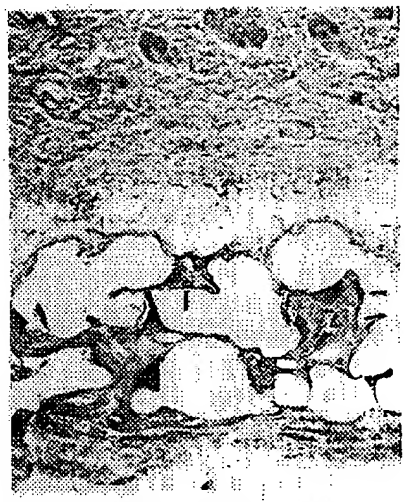


Fig 9.—Porous polyethylene (Plasti-Pore) implant in subcutaneous tissues of forehead. Clear white areas are porous polyethylene, and around them, connective tissue and capillaries fill spaces (pores). There are few histiocytes and giant cells. Material (I) appears securely anchored at surfaces (hematoxylin-eosin, ×64).

tions of the outer surface, particularly in the six-week specimens; with time, few of these cells were observed. The implants did not seem to be embedded securely in the tissue (Fig 3).

The microscopic findings of the industrial membrane material were similar. There was slight tissue attachment to the surface, but there was no evidence of cellular or connective tissue penetration of the material. A few histiocytes and giant cells were seen at the surface of the material. The implants did not seem to be anchored firmly into the surrounding tissue, but the tissue surrounding the implants appeared healthy (Fig 4).

In contrast, the Gore-Tex cylinder material, which has larger internodal spaces (30 μm), seemed to be anchored firmly in the surrounding tissue (Fig 5). A few more histiocytes and giant cells were seen along the surface of the implant. The interstices of the cylinder material were partially filled with a thin collagenous matrix, fibroblasts, and functional capillaries. Tissue appeared to be attached to the surface of the implant, and this extended into the interstices of the material. Although the cylinder material was firmly anchored in the tissues, it could easily be dissected from the subcutaneous tissues and removed en bloc.

Numerous macrophages and foreign-body giant cells surrounded the polytetrafluoroethylene carbon implants and lay within the spaces of the material. Fibrous connective tissue and capillaries were seen at the surface of the material and penetrated the spaces within the material. The implants appeared to be anchored firmly but somewhat fragmented, and little of this was a cutting artifact (Figs 6 and 7).

A few histiocytes and giant cells were seen around the porous polyethylene implants. Slight tissue attachment to the surface of the material was noted; however, connective tissue with functional capillaries permeated the large pores from surface to surface. Microscopically, the porous polyethylene implants would appear to be anchored firmly in the tissue (Figs 8 and 9). Nevertheless, there were high incidences of flap necrosis and extrusion of the implants, probably because of the hardness and lack of flexibility of the material.

COMMENT

Most plastic and reconstructive surgeons prefer autogenous bone or cartilage. Autogenous tissue cannot always be obtained, additional time is consumed at operation, and additional morbidity is associated with the donor sites. Allogeneic cartilage and bone can be prepared satisfactorily by either freezing or irradiation and can be preserved; however, these procedures are certainly not as simple as the use of prepackaged synthetic materials, and the outcome is not as predictable.[9] In addition, great care must be used to keep banked materials sterile. Given those situations in which autogenous or allogeneic grafting material is not available in sufficient quantities or at all, it is important to have synthetic materials that are safe and compatible.

The Gore-Tex cylinder material with 30-μm internodal spaces and thin and flexible fibrils seems to be more ideal than polytetrafluoroethylene carbon or porous polyethylene implants. The internodal spacing and relatively long, thin fibrils permit secure anchoring of the implants at the surface and by connective tissue ingrowth. It is biocompatible, because histiocytic and foreign-body giant cell reactions in the surrounding tissues are minimal. It retains its structural integrity, can be shaped by carving with a sharp instrument, and is moderately soft. It would cushion direct impacts. The cylinder material did not appear to migrate, and it was not dislocated from the sites in the pinna that are subjected to continual trauma. There was no evidence of infection at any of the recipient sites. An average internodal spacing of 30 μm, which allowed tissue ingrowth, presumably would allow migration of WBCs and control of infection throughout the material. It can be removed easily, despite the tissue penetration and the supporting envelope of connective tissue.

Porous polyethylene was a good material to study for comparative purposes. In previous studies of porous polyethylene with pore sizes of 20 to 30 μm, comparable with that of the Gore-Tex cylinder material, the incidences of flap necrosis and extrusion were higher than those with polyamide mesh and polytetrafluoroethylene carbon implants.[10] In this study, the same problems were observed with the porous polyethylene material with a pore size of 175 μm. Porous polyethylene material is biocompatible and retains its structural integrity, but it is slippery and rigid. The rigid consistency of the material is probably responsible for the high inci-

dence of extrusion. Extrusion occurred, despite extensive permeation of the large pores and honeycombed configuration with viable connective tissue. In other words, excellent tissue infiltration was not necessarily consistent with stability and permanent incorporation into the surrounding tissues. In short, porous polyethylene material seemed to be rather easily dislocated with trauma; furthermore, it was not easily sculptured.

The blackness of polytetrafluoroethylene carbon material, even with a coating of Teflon, was readily apparent through both the skin of the ear and the thicker skin of the face and back. This is a serious drawback in facial plastic and reconstructive surgery, one that has been noted in clinical trials.[12-14] Of equal concern is the question of biocompatibility of the material; during this study, large numbers of histiocytes and giant cells were found throughout the material and in the surrounding connective tissue. Of even greater concern was the finding that the polytetrafluoroethylene carbon appeared to disintegrate and lose its structural integrity. A fairly thick layer of connective tissue around the material stabilized it. In the long term, it would seem that a great deal of scar would form around and throughout the material. The implant would be difficult to remove in the presence of infection. The incidences of implant extrusion and necrosis of the ear flap skin were similar to those of porous polyethylene. However, the material is easily sculptured.

Neither necrosis of the overlying skin nor extrusion occurred with any of the synthetic materials inserted into the subcutaneous pockets beneath the skin of the face and back, presumably because the skin and subcutaneous tissues overlying the implants in these regions are fairly thick, the sites are relatively immobile, and the blood supply is good. In contrast, the rabbit pinna is a much better site for more subtle observations, for critical analysis, and for clear observations of the fate of the various implants. The implants in this site are covered by thin skin and are subjected to repeated bumping and trauma. I think that the result of long-term observation for necrosis of the skin overlying the implant and for partial or total extrusion of the implant is a good measure of what will happen beneath the skin of the nose. The highest incidence of skin necrosis in this study and in previous studies occurred with the most rigid implants, namely, porous polyethylene and Silastic. The relatively high incidences of flap necrosis and extrusion with the Teflon-coated polytetrafluoroethylene carbon material seemed to be caused by the intense, chronic, foreign-body inflammatory response around the material rather than the consistency of the material.

In summary, the best balance of porosity (and tissue ingrowth), compatibility (cellular reaction), consistency, structural integrity, and ease of removal is found with the Gore-Tex cylinder material with an average internodal space of 30 μm. The material is not yet commercially available for routine facial plastic and reconstructive surgery, but it certainly appears to have a favorable future. Clinical studies will define that potential more clearly.

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